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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/273,098	03/19/99	TESSIER-LAVIGNE	M	UC97-244-2

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RICHARD ARON OSMAN
SCIENCE & TECHNOLOGY LAW GROUP
75 DENISE DR
HILLSBOROUGH CA 94010

EXAMINER	
ALLEN,M	
ART UNIT	**PAPER NUMBER**
1631	9

DATE MAILED: 12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/273,098	Applicant(s) TESSIER-LAVIGNE ET AL.	
	Examiner Marianne Allen	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/12/00 .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 and 6-26 is/are pending in the application.

4a) Of the above claim(s) 10,11,17,18,25,26 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 and 6-9,12-16,19-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Claim 5 has been cancelled. Claims 12-26 have been newly added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 9/12/00 have been fully considered but they are not persuasive.

Applicant's election of Group I in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that applicant has requested rejoinder of the method of use claims after allowable subject matter has been indicated for the products. No products are presently allowable.

Claims 10-11, 17-18, and 25-26 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The rejection of claims 1-4 and 6-7 under 35 U.S.C. 102(e) as being anticipated by Artavanis-Tsakonas et al. (U.S. Patent No. 5,789,195) is withdrawn due to amendment of the claims to recite "natural sequence." The fragments disclosed by the '195 patent do not appear to be naturally occurring proteolytic fragments.

Claims 1-4, 6-7, 12-14, and 19-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No.

6,046,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim isolated fragments of slit polypeptides. It would have been obvious and routine for one of ordinary skill in the art to make a composition of the polypeptide with a pharmaceutically acceptable excipient. The product by process claims are examined and evaluated as a product. Table 1 in the '015 patent discloses the human Slit-2 sequence.

Applicant's arguments and the Goodman Declaration are unpersuasive. Applicant has not demonstrated that the claims of the patent do not encompass the presently claimed embodiments. No particular activity is required in either set of claims. No particular fragment is required by either set of claims; however, the claims clearly contain overlapping embodiments which is the essence of double patenting. Inclusion of the limitation "natural sequence" does not obviate this rejection.

Claims 1-4, 6-9, 12-16, and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record as applied to claims 1-4 and 6-9. Inclusion of the phrase "natural sequence" in the claims does not obviate this rejection. The portions of the specification pointed to in support of this phrase provide no clear definition of its metes and bounds. It appears that applicant may be intending to limit the claims to naturally

occurring proteolytic forms of Slit proteins (which have not been described or identified) and to exclude man made truncations. However, this is unclear. It is noted that applicant's disclosure of possible processing sites and/or "inference" or "prediction" of possible sites by alignment does not adequately identify naturally occurring proteolytic fragments. These proteolytic forms may or may not exist in nature. As far as the examiner has been able to determine, applicant has specifically identified a single naturally occuring proteolytic fragment, namely an amino terminal cleavage product of approximately 140 kD for human Slit-2 when produced in COS cells. See page 3. This fragment is associated with the membrane and must be extracted. The peptides of Tables 1-2 appear to be excluded by the claim language and applicant's arguments.

The specification fails to define the metes and bounds of what is considered to be a Slit protein. Thus, it cannot be known what the naturally occurring proteolytic forms would be, particularly if they differed depending upon the cell used to produce the protein recombinantly.

Note that neither applicant's arguments nor the Goodman Declaration demonstrate an art acknowledged definition in terms of structure and function for the claimed proteins.

Note that the claims do not require any particular activity for the protein.

As stated in the previous Office action, the specification states that Slit-N polypeptides are proteolytic fragments of Slit proteins which stimulate elongation and branching of neuronal axons (page 2, lines 9-10). The specification states that Slit-N polypeptides encompass N-terminal fragments of Slit proteins which promote axon branching (page 3, lines 2-3). Note that these two disclosures are inconsistent with respect to providing a clear definition by structure and/or

function for the broad class of proteins. Furthermore, the specification does not make clear what distinguishes an N-terminal fragment from other fragments of the protein. It does appear from the claim terminology that applicant means to exclude the naturally occurring, full length protein and as discussed above perhaps limit the claims to naturally occurring proteolytic forms of Slit proteins so as to exclude man made truncations. However, it remains unclear how this is to be interpreted with respect to any leader sequence or prosequence (the preproprotein) that may exist. That is, would the mature sequence meet the definition of a Slit-N polypeptide? Note that this would still be a naturally occurring proteolytic form. Applicant does not appear to address any of these points.

It is maintained that the specification provides no clear and limiting structural or functional definition to establish the metes and bounds of what constitutes an isolated Slit, Slit-N, or natural sequence Slit-N polypeptide.

Claims 3, 6-9, 12, 14-16, 20, and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing in reciting "contained in a pharmaceutical composition." It appears that applicant may have intended to claim a composition comprising the polypeptide of claim 1 and a pharmaceutically acceptable excipient; however, the claim language does not make this clear. Furthermore, the limitation "pharmaceutical composition" implies an intended use and/or a

therapeutic amount for such an intended use which are not presently limitations in the claim. Applicant has not addressed these points. See also claim 20.

Claims 6-9 are directed to pharmaceutical compositions and recite "therapeutically effective amounts." However, no specific condition to be treated is recited in the claim and as such it cannot be determined what amounts of polypeptides the claims encompass. Claims 8-9 also fail to indicate the desired therapeutic effect or amount of the other neuroactive agent or NGF required. See also new claims 12, 14-16, 20, 22-24. Note that the claims do not recite the therapeutic effect argued by applicant and thus read on any therapeutic effect.

Claim 14 appears to be identical in scope to claim 7. Clarification is requested.

Claims 1-4, 6-8, 12-15, and 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodman et al. (U.S. Patent No. 6,046,015).

Goodman et al. discloses human Slit-1 polypeptide fragments and pharmaceutical compositions thereof. Compositions containing collagen fibers are deemed to meet the limitation of another neuroactive agent as such fibers would have been routinely used to provide a substrate for neuronal growth. (See abstract; claims; column 4, lines 30-65; column 17, lines 5-50.) Applicant's arguments are unpersuasive as Goodman et al. teaches producing the proteins recombinantly which would result in the naturally occurring proteolytic forms encompassed by the

instant claims. Furthermore, natural sequence fragments are disclosed. See column 4, lines 59-61.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning the formalities of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 308-0009.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
AU1631